

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:	:	
	:	Confirmation No. 3314
Gerald Cagle et al.	:	
	:	Group Art Unit: 1618
Application No. 10/715,055	:	
	:	Examiner: Fay, Zohreh A.
Filed: November 17, 2003	:	
	:	Atty Dkt No.: 007109.00001
For: METHOD OF TREATING	:	
OPHTHALMIC INFECTIONS WITH	:	
MOXIFLOXACIN COMPOSITIONS	:	

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Customer Service Window  
Randolph Building  
401 Dulany Street  
Alexandria, VA 22314

Sir:

The documents listed on the attached PTO forms PTO/SB/08a are being brought to the attention of the Examiner. The Examiner is requested to initial the space adjacent the document's entry on the form and to return a copy of the initialed form to confirm that the document has been considered and has been officially made of record in this application.

As was noted in Appellants' appeal brief, an opposition was filed in the European Patent Office (EPO) against EP 1,117,401 B, the European counterpart of the parent of the subject application. On October 30, 2006, the Opposition Division issued a final decision favorable to the patentee (copy previously submitted). That decision was reversed by the Technical Board of Appeal ("Board") in a opinion issued April 30, 2009, a copy of which is submitted herewith. The Board failed to give proper weight to the record evidence demonstrating the need for

antibiotics in ophthalmic formulations to have a broad spectrum of coverage against all important ocular pathogens, particularly the sight-threatening pathogen *Pseudomonas aeruginosa*, because ophthalmic infections are treated and prevented empirically, meaning that the identity of the pathogen causing the infection is not known when treatment or prophylaxis is initiated. See Stroman Dec. ¶¶ 4-5. For this reason, moxifloxacin – which had been reported to exhibit 2- to 8-fold less activity than ciprofloxacin against *Pseudomonas aeruginosa* – was not regarded as a viable candidate for treating ophthalmic infections at the time of invention. See Stroman Dec. ¶¶ 10-12.

A second IDS submission filed concurrently herewith includes an article authored by Bauernfeind et al., which was cited during prosecution of a counterpart application in Brazil.

The Examiner is invited to telephone the undersigned at the number listed below if she has any questions concerning this submission.

Respectfully submitted,

Date: July 27, 2009

By: /Paul M. Rivard/  
Paul M. Rivard  
Registration No. 43,446  
BANNER & WITCOFF, LTD.  
1100 13<sup>th</sup> Street N.W., Suite 1200  
Washington, DC 20005-4051  
(202) 824-3000 (telephone)  
(202) 824-3001 (facsimile)